



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,998	10/16/2003	Patrick J. Sweeney	029815-0103	7428
26371 7590 02/11/2009 FOLEY & LARDNER LLP 777 EAST WISCONSIN AVENUE MILWAUKEE, WI 53202-5306				
EXAMINER				
MILLER, CHERYL L				
ART UNIT		PAPER NUMBER		
3738				
MAIL DATE		DELIVERY MODE		
02/11/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/686,998

Applicant(s)

SWEENEY, PATRICK J.

Examiner

CHERYL MILLER

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 10, 12, 18, 22, 28, 37, 43, 66 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-7, 9, 11, 13, 15, 21, 23, 25, 27, 30, 32, 34, 36, 38, 39, 41, 61, 63, 68 and 69 is/are rejected.
- 7) ☒ Claim(s) 8, 17, 29, 64 and 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-813)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1,3,5-13,15,17,18,21-23,25,27-30,32,34,36-39,41,43,61,63-66 and 68-70.

DETAILED ACTION

1.131 Declaration

The declaration filed on November 7, 2008 under 37 CFR 1.131 is sufficient to overcome the rejection of claims 1, 3, 5-9, 11, 13, 15, 17, 21, 23, 25, 27, 29, 30, 61, 63, 64, 68, and 69 over Buttermann (US 2005/0113924 A1) and claims 1, 5, 7, 11, 13, 61, 63, 68, and 69 over Malek (US 2005/0071007 A1).

The declaration filed on November 7, 2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the rejection of claims 32, 34, 36, 38, 39 and 41 over Buttermann (US 2005/0113924 A1) and claims 32 and 38 over Malek (US 2005/0071007 A1). The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Buttermann reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The drawings submitted do not evidence the claimed subject matter of claims 32, 34, 36, 38, 39, and 41, particularly the interchangeability of different shaped disc prostheses and having different disc prostheses of different shapes.

Response to Arguments

Applicant's arguments filed November 7, 2008 have been fully considered but they are not persuasive.

The applicant has argued that Hedman et al. (US 4,759,769) does not disclose a "support". The examiner disagrees. The "support" is considered to be right 72+74 which

provides spacing between plates and carries the load transferred from the plates, thus acting to supports the plates. The applicant has also argued that a first portion is not slidably received in a second portion. The examiner disagrees. Portion 74 is slidably received within portion 72. As the coil winding is larger in 72, each winding of 72 expands/lengthens at a faster rate than the expansion/lengthening of windings 74, thus 72 slides relative to 74. As the expansion/lengthening of the coil windings take place (sliding), the height is adjusted. This height adjustment is a result of the forces placed on the plates by the vertebrae or the surgeon during manipulation. This rejection has been maintained.

The applicant has argued that Butterman (US 5,827,328) in view of Hedman (US 4,759,769) is not an obvious combination as Butterman teaches away from the combination of elements (specifically a pedicle screw retainer on the plate or support). The examiner disagrees. Butterman teaches a spinal implant system substantially as claimed comprising all elements including a pedicle retainer (mechanical and other attachments), however is silent to mention the location of the pedicle retainer. Hedman teaches an example of pedicle retainers located on endplates of spinal devices. Butterman does not teach away from pedicle screw retainers. Butterman notes that mechanical fasteners are not required or necessary, however this does not exclude their use. In fact Butterman further notes that although they are not required (since the Butterman device is believed to be already securely fastened), they still may be used as supplemental fastening structures (col.7, lines 16-20) to increase stability. Thus Butterman does not teach away from the use of pedicle screw retainers and is considered combinable with Hedman. This rejection has been maintained.

As new rejections have also been applied, this action is NON-FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 36, 38, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Buttermann (US 2005/0113924 A1, cited previously). Buttermann discloses a spinal implant system (figs.15, 17, 21, 24) comprising a vertebral prosthesis (fixation member; 214 for example) comprising a support (224) with a first portion slidably received in a second portion (see figs) and prosthesis endplate (252), an artificial disc comprising a disc endplate (244) and disc core (242+240), the artificial disc interlocked with the prosthesis endplate (by recess and flange, morse taper connection), an a pedicle screw retainer (holes in fixation member; P0095; P0106) having top, bottom and aperture (246, 510) for a screw (310) capable of penetrating a pedicle. Buttermann discloses different disc prosthesis by having different amounts of spring and spring constants (P0025, P0139).

Claims 1, 3, 5-7, 32, 34, 38, 61, 63, and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Hedman et al. (US 4,759,769, cited previously). Hedman discloses a system (fig.1, 2) comprising a vertebral prosthesis having a support shaft (right 72+74) having a first portion (74) slidably receiving in a second portion (72), and a prosthesis endplate (26) and a

spinal disc comprising a disc endplate (28) and disc core (left 72+74), an interlock structure (recess 34 or 52) and a pedicle screw retainer (46) coupled to the support (26) the retainer having a top, bottom, sidewall and aperture configured to receive a pedicle screw (94, 96, screws adapted for placement into the pedicles). Hedman discloses an adjustable height support shaft (shaft 74+72 is a spring and compresses to different heights, the two springs having different spring constants thus slide past one another during height adjustment). It is noted with respect to claim 32, first and second discs are not positively claimed since the phrase implanted adjacent either a first or second disc is intended use language and the claim does not define the discs to be part of the spinal implant system, only capable of use with disc implants, thus disc implants need not be present in the prior art. Hedman's core (72) does not rotate relative the endplate (26).

Claims 32 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Malek (US 2005/0071007 A1, cited previously). See figures 25-28. Malek discloses a support shaft (240+232) having a first portion (232) slidably received (alternate to threaded connection is disclosed a saw tooth connection thus slidable, P0049, P0071), in a second portion (240), first prosthesis endplates (286), an artificial disc having a core (302) and disc endplate (270), the disc (270+302) coupled to the prosthesis endplate (286) by an interlocking structure (complimentary surfaces, concave/convex). Malek discloses a pedicle screw retainer (tab 268 or portion of baseplates, see P0054) for receiving a screw (270; fig.28) capable of extending through a pedicle. Malek discloses use with different disc prostheses (P0007, P0008).

Claims 1, 5-7, 9, 11, 13, 15, 32, 34, 38, 39, 41, 61, 63, 68, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Berry (US 5,895,428, cited previously). Berry discloses a spinal implant (see figs.8-10) comprising a support (105+109) and a prosthesis endplate (121), the support having a first portion (109) slidably received within a second portion (105; screws in, thus slides helically relative one another), the height may be adjusted by sliding the first portion (109) relative second portion (105); a disc prosthesis comprising a disc endplate (bottom 35 located below 121) and disc core (bottom 13) coupled to the disc endplate (see fig.9), the disc (13+35) coupled to the prosthetic endplate (121) to allow motion; and a pedicle screw retainer (105 also may function to hold a pedicle screw 108; col.7, lines 1-4) coupled to the prosthetic endplate (121) having a top, bottom and side, an aperture (where screw 108 is inserted) in the side. Berry further discloses a second disc and endplate (upper 13+35, above 109).

Claims 1, 3, 5-7, 9, 11, 13, 15, 21, 23, 25, 27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertagnoli (US 5,480,442). Bertagnoli discloses a spinal implant system (see figs.5a, 5b, 8, 9) having many shown and disclosed features that may be combined or interchanged. Bertagnoli's implant comprises a support (102+103 or 57+59) and a prosthesis endplate (51 in fig.5a or 109 or 90 in figs.8, 9), the support having a first portion (103 or 59) slidably received within a second portion (102 or 57), the height may be adjusted by sliding the first portion relative second portion; a disc prosthesis comprising a disc endplate (97 or 53) and disc core (52 or 111 or 95) coupled to the disc endplate (see fig.5a, 8, 9), the disc (111 or 95 or 52) coupled to the prosthetic endplate (109 or 90 or 51) to allow motion (motion occurs during trialing, prior to hardening of adhesive or cement); and a pedicle screw retainer (support also

may function to hold a pedicle screw; has perforations in the mesh structure capable of housing a screw; col.2, lines 28-31) coupled to the prosthetic endplate and having a top, bottom and side, an aperture (hole in mesh) in the side.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buttermann (US 2005/0113924 A1, cited previously). Buttermann discloses the spinal prosthesis substantially as claimed (see above). Buttermann discloses the prosthesis endplate and support to be attached, however is silent to mention how they are connected. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have one of the claimed connections (threaded, snapped, or twisted), since such are common attachment means. It would be common sense to use any form of attachment, as Buttermann is silent to a specific attachment method.

Claims 1, 3, 6, 7, 9, 11, 13, 15, 32, 34, 38, 39, 41, 61, 63, 68, and 69 rejected under 35 U.S.C. 103(a) as being unpatentable over Buttermann (US 5,827,328, cited previously) in view of Hedman (US 4,759,769, cited previously). Buttermann discloses a spinal implant system (figs.7) comprising a vertebral prosthesis (fixation member; 14 for example) comprising a

support (24) with a first portion slidably received in a second portion (67, 65) and prosthesis endplate (31 or 32), an artificial disc comprising a disc endplate (42 or 44) and disc core (40 or 40+42), the artificial disc interlocked with the prosthesis endplate (by adhesive). Buttermann discloses the implant system substantially as claimed. Buttermann discloses pedicle screw retainers (supplemental mechanical or other attachments, col.7, lines 16-20), however does not disclose specific locations of pedicle screw retainer (on the support or endplate). Buttermann does disclose the option of supplemental anchors such as screws, but is silent as to where they are attached and how. Hedman teaches in the same field of spinal implant systems, the use of a tab (46) with aperture on an endplate for attachment of a screw for better securement (col.3, lines 50-69). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Buttermann's vertebral prosthesis with disclosure of possible anchoring means with Hedman's particular anchoring means (tabs with apertures considered pedicle screw retainers with top, bottom and aperture) in order to provide a prosthesis with increased anchoring capabilities.

Referring to claims 6, 15, 34, and 41, Buttermann discloses the prosthesis endplate and support to be attached, however is silent to mention how they are connected. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have one of the claimed connections (threaded, snapped, or twisted), since such are common attachment means. It would be common sense to use any form of attachment, especially common means such as threaded and snapped, as Buttermann is silent to a specific attachment method.

Allowable Subject Matter

Claims 8, 17, 29, 64 and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738

